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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 549,463	04 14 2000	Guus Hatteboer	4038.IUS	8657

7590 07 02 2002
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EXAMINER

MITRA, RITA

ART UNIT	PAPER NUMBER
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1653

DATE MAILED 07 02 2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/549,463

Applicant(s)

HATTEBOER ET AL.

Examiner

Rita Mitra

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3, 5-7, 11, 13, 14, 22 and 73-97 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1, 3, 5-7, 11, 13, 14, 22 and 73-97 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Status of the Claims

Applicants' amendment and response to office action dated October 2, 2001, in paper # 8 filed on January 22, 2002 is acknowledged. Applicants have elected Group I, claims 1, 3, 5-7, 11, 13, 14 and 22 without traverse. Claims 2, 4, 8, 9, 18-21, 23-34, 37-41, 43, 45, 47, 49, 51-54, 57, 58, 63, 64, 69-72 have been canceled. Claims 5, 7, 11, 13 and 22 have been amended and entered. New claims 73-97 have been added. Therefore, claims 1, 3, 5-7, 11, 13, 14, 22, 73-97 are currently pending and are under examination.

Upon further consideration of amended claims and new claims a restriction is required as follows:

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 3, 5-7, 11, 13 14, 73-86 and 97 are drawn to a method for producing a proteinaceous substance in a eukaryotic cell comprising providing a cell having nucleic acid sequence encoding adenoviral E1A protein, providing said cell with a gene encoding recombinant proteinaceous substance, a recombinant mammalian cell; classified in Class 536, subclass 23.1; Class 435, subclasses 69.1, 455, 252.3, and 320.1.

Should Group I be elected, applicants are required to select one virus for the selection of viral protein. Because each type of protein produced by a method is a different to each other because of the different product.

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- II. Claim 22 is drawn to a recombinant mammalian cell immortalized by the presence of one adenoviral E1A protein, comprising a nucleic acid in a functional format for expressing one variable domain of an immunoglobulin; and a nucleic acid derived from an adenovirus encoding one E1A protein; classified in Class 435, subclasses 69.1, 455, 252.3, and 320.1, class 530, subclass 387.1
- III. Claims 88-91 are drawn to a method for producing a proteinaceous substance in a eukaryotic cell comprising providing a cell having nucleic acid sequence encoding adenoviral E1A protein, further comprising a sequence encoding adenoviral E2A protein, providing said cell with a gene encoding recombinant proteinaceous substance, a recombinant mammalian cell; classified in Class 536, subclass 23.1; Class 435, subclasses 69.1, 455, 252.3, and 320.1.
- IV. Claims 92-95 are drawn to a recombinant erythropoietin molecule produced by the method of claims 1 or 6; classified in Class 530, subclasses 350.
- V. Claim 96 is drawn to a recombinant mammalian cell immortalized by the presence of one adenoviral E1A protein, comprising a nucleic acid in a functional format for expressing one variable domain of an immunoglobulin; and a nucleic acid derived from an adenovirus encoding one E1A protein, further comprising a nucleic acid encoding adenovirus E1B protein; classified in Class 435, subclasses 69.1, 455, 252.3, and 320.1, class 530, subclass 387.1

The inventions are distinct, each from the other because of the following reasons:

Groups I and III are different methods. Methods of making products differ with respect to ingredients, method steps, and endpoints; methods of I and III differ by additional adenoviral E2A protein. Therefore, each method is patentably distinct.

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Groups I, III and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product, the protein can be made using an amino acid synthesizer.

Inventions I, III and II, V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the claimed recombinant cell can be used in a materially different process such as in the method of any one of the invention I and III or in the recombinant production of polypeptides. Therefore, the inventions are distinct.

Inventions II, V and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the recombinant cell of group II and V and the protein of group IV are not necessary to use together for the practice of claimed method of I and III. Therefore the inventions are distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

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Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).


Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (703) 605-1211. The Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Christopher Low, can be reached at (703) 308-2923. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Rita Mitra, Ph.D.

June 21, 2002


KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER